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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,794	12/08/2005	Federico Mailland	622-89	7507

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,794	MAILLAND, FEDERICO	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-29 and 48-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-29 and 48-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0808*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 July 2008 has been entered. In addition, the Declaration by the instant inventor, and the certified copy of the foreign priority document - both filed 21 July 2008, have been received and entered.

Claims 25-29 and 48-79 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 26, 49, 58, 63, 65, 67, 68, 71-73, and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Godbout (US 2004/0013622).

A method for the treatment of onychoschizia in a patient in need of such treatment via administering to said patient a topical composition comprising at least one *Equisetum* extract and at least film forming agent is claimed.

Godbout teaches a method of topically applying a composition comprising an *Equisetum* (preferably *Equisetum arvense* - also known as horsetail) extract (as a source of silica) - including at a concentration of 10.1% by weight and 3% by weight of the overall composition (as shown in Examples 1 and 3), to a female patient having extremely brittle nails (thus, "a patient in need of such treatment" since such a patient either would have onychoschizia or at least be prone to the development thereof), whereby the topical composition improved the overall health of the nails including improving the flexibility and moisture content as well as reducing the breakability thereof. The topical compositions taught by Godbout comprise high concentrations of one or more conventional pharmaceutical (physiological) carriers such as water - including at a concentration of 51.6% by weight of the overall composition (as shown in Example 3) The topical compositions taught by Godbout also comprise other ingredients (such as *Ulva lactuca* extract, DMDM hydantoin, aloe extract, hydrolyzed keratin, etc) which would inherently act as film forming agents. That is, the instant specification defines film forming agents as "components of a binder which are essential for forming a film, i.e., a thin layer or cover" (see, e.g., last few lines on page 5 the instant specification). Accordingly, the other ingredients within the topical composition taught by Godbout (such as *Ulva lactuca* extract, DMDM hydantoin, aloe extract, hydrolyzed keratin, etc) would inherently act as binder components therein since they would inherently act to bind the composition together as a topical skin layer/covering - e.g., including with respect to providing structural integrity and stability thereto (especially as compared to not having these other components therein). See entire Godbout reference including, e.g., paragraphs [0006]-[0012], [0025]-[0037], [0042], [0044]-[0051], and claims.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 26, 49, 58, 63, 65, 67, 68, 71-73, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbout (US 2004/0013622) and the admitted state of the art,

Godbout beneficially teaches a method of topically applying a composition comprising an *Equisetum* (preferably *Equisetum arvense* - also known as horsetail) extract (as a source of silica) - including at a concentration of 10.1% by weight and 3% by weight of the overall composition (as shown in Examples 1 and 3), to a female patient having extremely brittle nails, whereby the topical composition improved the overall health of the nails including improving the flexibility and moisture content as well as reducing the breakability thereof. The topical compositions taught by Godbout also comprise high concentrations of one or more conventional pharmaceutical (physiological) carriers such as water - including at a concentration of 51.6% by weight of the overall composition (as shown in Example 3). Godbout also teaches the inclusion of amino acids therein, and that the topical composition may further comprise other additives including antibacterial agents, antifungal (anti-mycotic) agents, and fragrances (aroma substances) therein; and that the composition may be in a cosmetic form such as a cream, foam, or gel (all of which also reasonably read upon a "film forming agent" - in addition to the other ingredients discussed above under USC 102 that also read upon film forming agents, since these cosmetic forms would also bind the active ingredients therein as well as provide a skin

layer/cover (with respect to the definition of "film forming agent" provided by the instant specification, as discussed *supra*). See entire Godbout reference including, e.g., paragraphs [0006]-[0012], [0025]-[0037], [0042], [0044]-[0051], and claims. Godbout does not expressly teach treating a subject having onychoschizia with such a composition.

As readily admitted by Applicants, onychoschizia (aka lamellar splitting) and ungual brittleness is a wide spread condition found in 27-35% of normal adult women, that it affects mainly housewives, workmen, and workwomen, and that exogenous factors that contribute to onychoschizia include people who carry out a great deal of housework including those whose nails are repeatedly soaked in water and then dried (see, e.g., pages 2-3 of the instant specification).

It would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to topically apply a composition comprising an *Equisetum* (preferably *Equisetum arvense* - also known as horsetail) extract - as a source of silica (including within the instantly claimed weight percentage ranges thereof), as well as a "film forming agent" (such as the ingredients beneficially taught by Godbout that reasonably read thereon, as discussed above) to a subject having brittle nails - including brittle nails due to having onychoschizia, based upon the beneficial teachings provided by Godbout with respect to its demonstrated ability to therapeutically improve brittle nails (as discussed above), especially given that onychoschizia (aka lamellar splitting) and ungual brittleness, as readily admitted by Applicant, is a wide spread condition found in 27-35% of normal adult women, that it affects mainly housewives, workmen, and workwomen, and that exogenous factors that contribute to onychoschizia include people who carry out a great deal of housework including those whose

nails are repeatedly soaked in water and then dried - making the topical application of the reference therapeutic nail composition by subjects having onychoschizia clearly obvious, especially among women who commonly encounter this nail condition.

Thus, the invention as a whole is clearly *prima facie* obvious over the cited reference and the admitted state of the art, especially in the absence of evidence to the contrary.

Claims 27-29, 48, 51-62, 64, 66-70, and 74-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbout (US 2004/0013622) in view of the admitted state of the art as applied to claims 25, 26, 49, 63, and 71-73 above, and further in view of Ramin (US 5,607,768) and Moeller et al (DE 19826953 - WPINDEX Abstract), and further in view of the PDR® for Herbal Medicines (1998) and Koniger (WO 94/25041 - Derwent abstract and machine English translation).

The Godbout reference and the admitted state of the art are relied upon for the reasons set forth above. Godbout does not expressly teach that the topical composition comprises a chitosan or derivative thereof as the film forming agent, a sulfur source such as the particular amino acids instantly claimed, or using a particular extraction solvent for preparing the *Equisetum* (horsetail) extract.

Ramin beneficially teaches applying a composition (such as in the form of a varnish - a well known film coating/layer) to the nails so as to decrease the cracking and splitting as well as improve the flexibility thereof, which comprises or may comprise chitosan and its derivatives as well as cystine (a sulfur donor amino acid - such as instantly claimed) as active agents capable of therapeutically improving the nails including with respect to protecting, hardening, revitalizing

and/or moisturizing the nails therein (each at a concentration of 0.01-5%). See entire document including, e.g., col 1, line 8 - col 2, line 50, and claims 6 & 19.

Moeller et al. beneficially teach various types of chitosan derivatives having improved water-solubility which are useful in cosmetic preparation such as nail lacquer (varnish) - see abstract.

The PDR® for Herbal Medicines reference beneficially teaches the well known usage of *Equisetum* (horsetail) for brittle fingernails and that comminuted herbal decoctions (water extract) or other galenic preparations (i.e., other solvents and/or extraction methods) are described for external (topical) use (see, e.g., column 2 of page 830)

Koniger beneficially teaches therapeutic *Equisetum* (horsetail) extract preparations for topically applying to nails, whereby the extracts are prepared via aqueous alcoholic extraction (see Derwent abstract and entire machine English translation).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further include the amino acid cystine (especially since Godbout expressly discloses the inclusion of amino acids therein), as well as chitosan or a water-soluble chitosan derivative (such as one or more of those instantly claimed) as active nail improving ingredients within a topical composition for treating brittle nails - including brittle nails due to having onychoschizia, based upon the beneficial teachings provided by Ramin and Moeller in conjunction, as discussed above (in conjunction with the beneficial teachings provided by Godbout and the admitted state of the art - as discussed *supra*). It would further have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ one of various extraction solvents in preparing such a therapeutic *Equisetum* (horsetail) extract -

such as a hydroalcoholic (aqueous alcoholic) or other alcoholic and/or galenic preparation thereof, based upon the beneficial teachings provided by the PDR® for Herbal Medicines and Koniger, as discussed above. The result-effective adjustment of particular conventional working conditions (e.g., determining appropriate amount ranges of such ingredients, using a particular chitosan derivative, and/or using a particular extraction solvent or dried preparation thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the above references before him/her as a guide.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references (as well as the admitted state of the art), especially in the absence of evidence to the contrary.

Applicants' arguments (including those presented with the Declaration filed 21 July 2008) concerning the USC 103 rejection set forth in the previous Office action are deemed moot in view of the new art rejections set forth above.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655